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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | |
|---|--|--|--|--|
| | 10/544,218 | CREPEL ET AL. | | |
| Office Action Summary | Examiner | Art Unit | | |
| | HAMID R. BADR | 1781 | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be time rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI | ely filed the mailing date of this communication. (35 U.S.C. § 133). | | |
| Status | | | | |
| 1) Responsive to communication(s) filed on <u>RCE</u>, 2a) This action is FINAL. 2b) This 3) Since this application is in condition for allowant closed in accordance with the practice under E | action is non-final. nce except for formal matters, pro | | | |
| Disposition of Claims | | | | |
| 4) ☐ Claim(s) 1-14 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-14 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or Application Papers | election requirement. | | | |
| 9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the off Replacement drawing sheet(s) including the correction of the off the oath or declaration is objected to by the Examiner. | epted or b) \square objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj | e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d). | | |
| Priority under 35 U.S.C. § 119 | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1/31/2011. | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ite | | |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/31/2011 has been entered.

Rejection of claims 1-12 under 35 U.S.C. 103(a) over Van Dijk et al. (GB 1,467,309) is withdrawn.

Rejection of claims 1-12 under 35 U.S.C. 112 second paragraph is withdrawn per applicants' amendment of claim 1.

New grounds of rejection are set forth below.

Claims 1-14 are being considered on the merits.

Claim Objections

Claims 1-14 are objected to for "characterized in that". Per patent practice in the United States; it is suggested to use 'wherein' instead of this phrase.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1781

2. Claims 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

- 3. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
- 4. Claims 13 and 14 recite "a fat content of at most 20% by weight".
 - a. Firstly, the phrase "at most" is not supported by the specification.
 - b. Secondly, While there are examples which use 20% fat (example 1), there is no support for the concept of a range of fat contents. Additionally, it is not clear what the lower limit of the fat would be., the specification discloses that skim milk and cream (400 g fat/ liter; i.e. 40% fat) are mixed and the mixture is homogenized.

Therefore, a mixture is being homogenized; not the cream obtained by centrifugation of milk and subsequent homogenization of the cream as known and practiced in the art. Further, the specification does not support the idea that 'homogenized cream' as customarily known in the art is used. The specification discloses that a mixture of skim milk, sugar and heavy cream (40% fat) is homogenized.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1781

6. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1, 6, 8, 13 and 14 are indefinite for "homogenized cream". The specification discloses that a mixture of skim milk, sugar and heavy cream (40% fat) is homogenized. Therefore it is not clear whether a homogenized mixture comprising cream is being used or a straight forward 'homogenized cream'; known conventionally in the art is being used.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 1. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amen et al. (WO 89/02702; hereinafter R1) with HU 58481 (hereinafter R2) and FDA Standards of identity for yogurt (hereinafter FDA Document) as evidentiary references.
- 2. R1 discloses the incorporation of cream into fermented yogurt product which can have added flavorings. R1 discloses that pasteurized cream, flavoring agents and coloring agents can be added to the fermented yogurt. R1 further teaches that for acceptable product stability, the fat content of the product should be in the range of 8-11% by weight based on the total weight of the finished product. (page 9, lines 19-33).

Application/Control Number: 10/544,218

Art Unit: 1781

3. R1 also discloses a formulation wherein cream is added to a fermented yogurt. The finished products are made in vanilla and strawberry flavorings. R1 discloses the mixing of cream into the yogurt bulk. Flavorings are then mixed into the yogurt containing cream. (Page 11-12, Example 1)

Page 5

- 4. While R1 does not expressly mention using homogenized cream, however, since the product disclosed by R1 is a shelf-stable aerosol dispensable yogurt, the stability disclosed and the homogeneity required by an aerosol dispensable product necessitates the incorporation of homogenized cream. It is also noted that in order to avoid creaming of the fat content when sitting on a shelf, the incorporated cream necessarily is a homogenized cream.
- The necessity of a homogenized cream in an aerosol system is further substantiated by R2. The aerosol dispenser of R2 employs homogenized cream (page 2). Therefore, the aerosol system disclosed by R1 must necessarily comprise homogenized cream.
- 6. It is noted that applicants have tried to show that the cream used by R1 has a much higher fat content than the cream used in the claimed invention. Then they conclude that since the fat contents are different, the homogenization parameters should be different, per an evidentiary reference disclosure applicants have presented, and consequently the cream used in R1 would not have been homogenized. In performing these calculations the applicants have made two assumptions; a. the fat in the product of R1 is coming only from the cream (and very little from skim milk) and b. that the product of R1 requires a fat content of 8-11%. It should be realized that the

Application/Control Number: 10/544,218

Art Unit: 1781

amount of fat does not have to be provided only by the cream and can be contained in the yogurt itself to start with per FDA Document for standards of identity for yogurt (page 1, lines 1-9). On the other hand, the present claims are not limited by fat content of the product. Therefore, the 7-14% cream required in claim 1 can be provided by any type of cream at any fat content.

Page 6

- 7. Since the stability of the product disclosed by R1 necessitates incorporating a homogenized cream, the free fat globules will intrinsically possess the particle diameter as disclosed. The fat globules associated with the yogurt (protein-fat network) will have the particle size of fat globules in a regular yogurt.
- 8. While R1 is silent regarding a chocolate flavored product or a vanilla flavored product containing chocolate chips, given that R1 discloses the incorporation of flavoring agents into the product, it is obvious to those of skill in the art that flavors such as chocolate flavor on its own or vanilla flavor and chocolate chips can be added to the formulations disclosed by R1.
- 9. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made to modify the yogurt product of R1 by adding either chocolate flavor or vanilla flavor containing chocolate chips to the product. One would do so to make various flavors of a base mix. Absent any evidence to contrary and based on the teachings of the cited reference, there would be a reasonable expectation of success in making a yogurt product containing added cream in various flavors.

Art Unit: 1781

10. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Dijk et al. (GB 1,476,309; hereinafter R3)

- 11. R3 discloses a process in which cream is admixed with an acidified milk product and whipped to produce a whipped topping. (page 1, col. 1, line 31 to col. 2, line 59).
- 12. While R3 does not expressly mention the incorporation of homogenized cream, in order for a whipped topping to be stable, the cream portion is expected to be homogenized.
- 13. R3 discloses a formulation where yogurt is mixed with cream to make a whipped topping. (Page 2, Example 2).
- 14. R3 teaches that additional sugar, flavors and other additives can be incorporated into the mixture. (page 2, col. 1, lines 15-18).
- 15. It is noted that the instant specification mixes skim milk, sugar and cream (40% fat) to make a diluted cream. However, the limitations of claims 13 and 14 requiring "at most 20% fat", can obviously be viewed as diluted cream.
- 16. Given that cream and yogurt are mixed to make the final product, the product would be a bimodal composition comprising free and bound-to-yogurt, fat globules. The size of fat globules can be varied employing various homogenization pressures known in the art.
- 17. Given that R3 discloses the addition of flavors of choice, it would be obvious to those of skill to incorporate flavors as presently claimed.
- 18. While the cream and yogurt proportions as disclosed by R3 are different from cream and yogurt proportions as presently claimed, since varying the cream and yogurt

Art Unit: 1781

proportions would result in different overruns (as disclosed by R3), different whipping properties, different flavors, and different caloric values, one would be motivated to changes those proportions for any of the mentioned reasons. Consequently, the cream and yogurt proportions as presently claimed can be manipulated to produce products of desirable properties.

- 19. Given that R3 teaches the mixing steps for various formulations, mixing in-tank and in-line as presently claimed would be obvious to those of skill in the art.
- 20. A yogurt product comprising cream and fermented yogurt as disclosed by R3 can be made with various flavorings. Therefore, it would have been obvious to one of ordinary skill in the art to modify the teachings of R3 by changing the cream and yogurt proportions in the formulations and incorporate various flavorings to make the yogurt of the instant invention. One would do so to take advantage of a variety of products regarding flavor, texture, whipping properties, and caloric value. Absent any evidence to contrary and based on the teachings of the cited reference, there would be a reasonable expectation of success in making a bimodal yogurt of different flavors as presently claimed.

Response to Arguments

Applicants' arguments are not persuasive.

- Applicants argue that in R1, the cream is optional.
 It should be realized that the word 'optional' does not exclude the teachings of R1. Therefore, cream may be incorporated in the composition.
- 2. Applicants' argue that R1 does not use homogenized cream.

Application/Control Number: 10/544,218

Art Unit: 1781

The examiner's position is that a homogenized cream is required for an aerosol system taught by R1. The evidentiary reference clearly indicates that when cream is used for an aerosol system, it has to be homogenized. On the other hand, R1 is being cited in an obviousness type rejection. It is clear that there are only two options for cream. It is either non-homogenized or homogenized. Selecting one over the other is well expected when an artisan weighs the benefits of one versus the other. A homogenized cream is more stable; a fact known in the art. The stability of fat globules when dispersed in an emulsion is much higher regarding oxidation. Dispersed fat globules also make a more balanced composition regarding the flavor. The uniform distribution of fat globules also assures that each portion of the composition provides the same amount of the components.

Page 9

3. Applicants have provided calculations to conclude that the cream used in R1 is a different cream regarding the amount of fat.

The fat content of cream varies with the type of cream. Regular cream contains abut 18-20% fat, while heavy cream can go to 40% or even higher. Again selecting one over the other one is obvious regarding the requirements of the compositions being prepared. As stated earlier, the "at most 20% fat" limitation of claims 13 and 14 are not supported by the specification. Further, the cream (itself) which is used by the Applicants is a 40% cream (400 g fat/liter). It is obvious that it can be diluted to any fat level by mixing with, for instance, skim milk. Additionally, the rejection is an obviousness type rejection in which the primary reference is teaching the post fermentation addition of cream to yogurt. Therefore, adding cream to yogurt is motivated. Further

manipulations regarding the type of cream, the concentration, the fat content of the composition prepared and the process parameters are obviously optimized for a desirable product. Such manipulations are well within the skill of the art.

4. Applicants argue that R1 requires a fat content between 8-11%, while the instant invention requires less fat.

The fat content of a composition may be adjusted to a desired level. Further, Applicants are assuming that the fat content taught by R1 is provided only by cream and skim milk. It should be realized that other ingredients can contribute to the fat content. The yogurt may contribute to the final fat content (see above under rejections); chocolate products, for example, are also fat contributors. Therefore, the assumption of calculations is not sound. As a result the fat content of cream used in R1 can vary.

5. Applicants have provided an evidentiary reference to substantiate that homogenized cream could not be used in the composition disclosed by R1. One of the reasons stated is that non-homogenized cream is better for whipping.

Being better for whipping does not mean that homogenized cream does not work in whipping products. All whipping creams, whether regular or heavy creams, on supermarket shelves, are homogenized cream.

6. Applicants argue that the stabilizing system in the composition of R1 is the combination of hydrocolloids; i.e. gums and that homogenization does not play a role.

In yogurt products, the base is always homogenized. Therefore, the stability of the composition as a whole in yogurt products is an additive effect of stabilizers such as gums and the homogenization process.

Art Unit: 1781

7. Applicants argue that the product of R1 would have different physical characteristics that the product claimed.

The issue being discussed is not whether the product of R1 is the same as the one being instantly claimed. What needs to be focused in the fact that in light of the teachings of R1, the presently claimed product would be obvious.

8. Applicants argue that when cream is used in products intended to be whipped, the cream should be non-homogenized, and that the cream of R1 should be non-homogenized.

Firstly, the product of R1 is not intended for whipping. R1 discloses that the dispensed product resembles whipped cream. Secondly, as mentioned above, all whipping cream products whether regular or heavy, on the supermarket shelves are homogenized cream. They are obviously intended for whipping.

9. Applicants argue that Van Dijk et al. (GB 1,476,309; hereinafter R3) is not directed toward aerosols.

Aerosol systems are not requirements of the present claims. R3 teaches of a bimodal composition produced by a post-fermentation addition of cream to yogurt.

10. Applicants argue that R3 discloses stabilizers for the stability of the product.

The presence or absence of stabilizers are not currently claimed. Therefore, whether R3 discloses such stabilizers are not relevant.

11. Applicants argue that cream concentration in the composition of R3 is much higher that the requirements of claim 1.

Art Unit: 1781

It is agreed that the cream concentrations disclosed by R3 is different that what is presently claimed. However, the rejection is an obviousness type rejection. The post-fermentation addition of cream to yogurt is disclosed by R3. Modification of the process parameters would be well within the skill of the art.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,163,802. discloses a process wherein a yogurt base is mixed with cream to make a base to which various flavoring can be added. WO 00/19831 discloses yogurt products of various flavors including vanilla and chocolate flavors. JP 11-276067 (machine translation) discloses yogurt products of low syneresis due to fat globules in a defined range.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1781

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/D. Lawrence Tarazano/ Supervisory Patent Examiner, Art Unit 1781 Hamid R Badr Examiner Art Unit 1781